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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Comments for November 15, 2004 Public Meeting
FDA's Pre-market Notification for New Dietary Ingredients

Collins, McDonald & Gann, P.C., is a law firm located in the state of New York that represents manufacturers, distributors, marketers and individuals in the sports and fitness supplement industry. Presenting these comments today is Alan Feldstein, Esq., Of Counsel to the firm who is located in California and Richard D. Collins, Esq., a principal of the firm. We thank you for the opportunity to share our thoughts. We welcome the opportunity to present comments on this matter which is of great importance to not only our clients, but to the segment of the industry we represent as a whole.

We have reviewed the Federal Register notice of this meeting. We have also read with great interest the recent Guidance for Industry on Substantiation for Dietary Supplement Claims as well as Dr. Crawford's recent statements, including his October 25th speech before the Council for Responsible Nutrition. While today's meeting is on the topic of new dietary ingredients and the 75 day pre-market notification process, rather than substantiation of label claims, our comments address a fundamental issue that is relevant to both topics. That issue is the *perception* that both FDA and the sports and fitness supplement industry have of each other and how that perception impacts the actions, philosophies and attitudes of both sides.

To begin with, the threshold question that remains a mystery is, under what circumstances must a pre-market NDI notification be filed? According to the Overview of Dietary Supplements posted January 3rd, 2001 on FDA's web site, DSHEA "requires that a manufacturer or distributor notify FDA if it intends to market a dietary supplement in the United States that contains a 'new dietary ingredient'." However, the law appears to say otherwise.

DSHEA actually says that a dietary supplement which contains a new dietary ingredient (NDI) shall be deemed adulterated unless it meets one of *two* criteria. One of those criteria is the submission of a proper pre-market NDI notification 75 days before marketing the product. The other, however, is that the dietary supplement "contains only

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dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered."

Industry has widely interpreted this language to require pre-market notice only if the product's new dietary ingredients are not present, unaltered, in the food supply. In fact, many manufacturers have chosen to decline to submit pre-market notice based upon their belief that their products comply with this provision of DSHEA, and in ten years FDA has never taken action under this provision with respect to a single product other than its one recent action regarding androstenedione. If FDA has an alternative interpretation of the statute, it has never explained it to industry. That is an example of the problem – a classic failure of communication which escalates distrust on both sides.

Further, in situations where all sides agree that pre-market notice is required, what sort of safety data does FDA require? One only has to look at FDA's web site on new dietary ingredients to understand the communication problem. If you look at the FDA web site to obtain guidance on what information the agency requires to approve or at least not object to a pre-market NDI notification you will find this language:

- *To date, we have not published guidance defining the specific information that the submission must contain. Thus, you are responsible for determining what information provides the basis for your conclusion.*

Moreover, the law states that new dietary ingredients which are not in the food supply can be introduced when there is a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will be reasonably expected to be safe. Despite pronouncements otherwise, the law does not state there should be a risk/benefit analysis as was done with ephedra. It does not suggest a requirement of zero risk. The process should not be a round-about way of allowing the agency to say "no," as is perceived by many of our clients. If the NDI process is to work within the parameters of DSHEA, then we would submit the following steps need be taken:

- Any guidelines that are propounded by FDA, and actions undertaken by FDA, must adhere to a reasonableness standard as was intended by Congress.

- Equally important, the standards must be applied in a transparent and reasonable manner with specific guidelines. In other words, if you submit the proper materials your ingredient will either be approved or not objected to.

In addition to these specific steps, it is our sincere hope that our comments today will also be the beginning of a dialogue to help change the perceptions that exist about FDA's attitudes towards dietary supplements. The debate here today is not whether or not there is a negative bias by FDA to the supplement industry, but rather the perception that such a bias exists and the perception that there is no one within the agency that is an advocate or supporter of the industry. We believe many of the issues raised by FDA for this meeting and in the recent draft guidance document on substantiation can be resolved with improved cooperation and communication.

In speaking with clients and other members of the sports and fitness supplement industry there is a sense of mistrust or that the process is stacked against anyone who wishes to file a pre-market notification for a new dietary ingredient or to make a claim. That is not true, you might hear the FDA say. That may be right. But if you were to poll our clients and others in the industry you would find that the perception exists. Why does it? For a moment put yourself in the shoes of a company in the sports and fitness supplement industry. Here are some of the things you would have seen in the last 10 years.

1. You have witnessed the publicizing of a group of anecdotal adverse event reports in such a manner as to give the impression that they conclusively support a claim that dietary supplements containing ephedra are dangerous. You then learn that the General Accounting Office in 1999, in its report entitled Dietary Supplements – Uncertainties in Analyses Underlying FDA's Proposed Rules on Ephedrine Alkaloids, concluded that FDA failed to establish that the proposed rule would have any public health benefit and that FDA did not establish that there was (or is) any need for the regulation. One may argue that this is old news and FDA was eventually right in banning the product, but since then this same issue arose with respect to Kava and as recently as several months ago FDA was criticized by the American Herbal Products Association (AHPA) on AERs involving bitter orange. AHPA was quoted as stating FDA is willing to regulate by anonymous press release and to be quite cavalier in its approach to truthfully informing the public about the safety profile of bitter orange. It is these actions that contribute to Industry's perception.

2. You are viewing FDA's newly heightened attention toward dietary supplements from a historical perspective dating back to the period of time before DSHEA, when legislators and federal judges were expressing concerns over FDA's activities against dietary supplements. For example, a Senate Committee found FDA was "distorting the law" to prevent safe supplements from being marketed, and a federal judge, in adjudicating a seizure action by FDA of encapsulated black currant oil, chided FDA for engaging in an "Alice In Wonderland Approach" to make an end-run around the statutory scheme.

3. You have seen androstenedione sold openly as a dietary supplement for many years, then suddenly removed from the market not only for safety reasons but for failure to file a pre-market NDI notification. Industry is suspicious of FDA's claim of safety because of the long delay. Even more puzzling is FDA's claim that it was not aware of evidence that the compound is present in the food supply. Studies confirm its presence in meat. All FDA had to do was look at the literature.

Thus, from our client's perspective, they have seen FDA take actions that they believe were not based on science, and when they ask "What are the rules?" that they have to play by, they are told there is no guidance for determining what information needs to be provided. This fosters a climate where many people believe that no matter what is submitted you will not get a fair hearing from FDA. Some industry representatives have told us that they believe that virtually all NDI notifications submitted

in the past year have been rejected. That perception creates an atmosphere fostering non-compliance with the law in which no one benefits.

Recently Dr. Crawford echoed these sentiments when he stated that the agency in the past had said "we are going to enforce the law, but you are going to have to guess what the standards are." We admire Dr. Crawford's candor, and he zeros in on the kind of atmosphere fostering mistrust and non-compliance. Our industry members are concerned because of the perception that the rule makers are biased against them. The question that is being asked by them is, "Are these guidelines and proposed rules being drafted in the spirit of DSHEA, or in the spirit of pushing the industry to a pre-market approval drug model?"

The latter would be detrimental to the American Public. The economic, technological and innovative advances which have guided this country and made it a leader happen when the framework of the rules are clearly set, while at the same time allowing ample room for innovation. Given our growing health crisis FDA should be encouraging innovation within a framework of safety.

Therefore, in addition to our specific proposals about NDIs we would also ask that FDA give serious consideration to three other proposals that will go a long way in improving its relationship with the sports and fitness supplement industry in general:

- FDA must, in a meaningful way, create lines of communication with all segments of the industry to better understand the different segments of the Industry and their needs and desires.

- FDA should take steps to communicate with and learn about the segment of the American population that uses sports and fitness nutritional supplement products so that it can create and implement its policies and procedures in a manner consistent with the public that it serves.

- We strongly recommend that FDA have an ombudsman within CFSAN, as it does with many other industries that it regulates. This would be someone who will investigate complaints from outside FDA and facilitate the resolution of disputes between CFSAN and the industry it regulates. Having someone who can help with communication between Industry and CFSAN will go a long way toward achieving a balance between the need to keep Americans safe and the right of Americans to make their own health decisions about dietary supplements.

Until there is better cooperation and communication between FDA and Industry and until there are people within FDA who support the use of dietary supplements this will continue to be a problem. To begin to solve the problem there needs to be an effort to change the perception that exists.

Respectfully Submitted,

Richard D. Collins	Alan H. Feldstein
Member of the Firm	Of Counsel to the Firm